



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1773]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Blood Products Advisory Committee. The general function of the Blood Products Advisory Committee is to provide advice and recommendations to the Agency on regulatory issues related to blood and products derived from blood. On the first day of the meeting, the Committee will provide advice regarding bacterial risk control strategies to enhance the safety and availability of platelets for transfusion. On the second day of the meeting, the Committee, supplemented with members from the Microbiology Devices Panel of the Medical Devices Advisory Committee, will function as a medical device panel to provide advice and recommendations to the Agency on classification of devices. The meeting will be open to the public.

DATES: The meeting will be held on July 18, 2018, from 8 a.m. to 5 p.m. and July 19, 2018, from 8 a.m. to 3 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, sections B and C), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a

disability, visitor parking, and transportation may be accessed at:

<https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Bryan Emery, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993-0002, 240-402-8054, bryan.emery@fda.hhs.gov; or Joanne Lipkind, Division of Scientific Advisors and Consultants, CBER, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6270, Silver Spring, MD 20993-0002, 240-402-8106, joanne.lipkind@fda.hhs.gov; or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the *Federal Register* about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting. For those unable to attend in person, the meeting will be also be available via webcast. The webcast will be available at the following link on both days: <https://collaboration.fda.gov/bpac0718/>.

SUPPLEMENTARY INFORMATION:

Agenda: On July 18, 2018, the Blood Products Advisory Committee will meet in open session to discuss and provide advice regarding bacterial risk control strategies for blood collection establishments and transfusion services to enhance the safety and availability of platelets for transfusion. The Committee will discuss the available strategies to control the risk of bacterial contamination of platelets with 5-day and 7-day dating, including bacterial testing

using culture-based devices and rapid bacterial detection devices and implementation of pathogen reduction technology.

On July 19, 2018, the Committee will function as a medical device panel. The Committee will meet in open session to discuss and provide advice regarding the device reclassification from class III to class II of nucleic acid and serology-based point-of-care and laboratory-based in vitro diagnostic devices indicated for use as aids in the diagnosis of human immunodeficiency virus (HIV) infection. The devices that will be discussed by the Committee during the meeting are post-amendment devices that currently are classified into class III under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)).

FDA intends to make background material available to the public approximately 2 weeks and no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 11, 2018. Oral presentations from the public will be scheduled between approximately 2:15 p.m. and 3:15 p.m. on July 18, 2018, and between 12:30 p.m. and 1:30 p.m. on July 19, 2018. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants,

and an indication of the approximate time requested to make their presentation on or before July 5, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 6, 2018.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Bryan Emery or Joanne Lipkin at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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